



Risk factors for complications of laparoscopic Nissen fundoplication

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Abstract

Background: Although the rate of complications from laparoscopic Nissen fundoplication is low and the adverse postoperative sequelae are well known, both are disturbing for the patient. Identifying risk factors could be helpful in the better selection of patients for this procedure.

Methods: A retrospective review of 126 patients with a mean follow-up period of 3.5 years was conducted. The patients' demographics, pre- and postoperative symptoms, and outcomes were analyzed and compared.

Results: Three groups of patients were distinguished: (group 1) 9 patients with intraoperative complications (5 with perforation, 3 with hemorrhage, 1 with pneumothorax); (group 2) 16 patients with postoperative complications (5 with severe dysphagia, 4 with failure, 2 with pneumonia, 2 with incisional hernia, 1 with intestine perforation, 1 with fundoplication herniation, 1 with infection, 1 with gastric ulcer); and (group 3) 101 patients without any complications. The patients' demographics, preoperative symptoms, and preoperative studies were comparable in all three groups. The body mass index (BMI) was significantly higher ($p < 0.05$) statistically in group 1 (32.4 kg/m^2) and group 2 (33.6 kg/m^2) than in group 3 (28.7 kg/m^2). However, the Visick grade and the subjective outcome were similarly good in all three groups.

Conclusions: Although preoperative studies and symptoms do not seem to predict complications of laparoscopic Nissen fundoplication, patients with an increased BMI were at increased risk for complications in this study. Therefore, such patients should be counseled appropriately regarding the greater likelihood of intraoperative and postoperative complications.

Key words: Complication — Nissen fundoplication — laparoscopy — BMI

Laparoscopic Nissen fundoplication, the most widely used procedure for surgical treatment of gastroesophageal reflux disease (GERD), has become the standard procedure in many centers. The rate of complications is low and decreases significantly with the surgeon's experience [4]. Failure rates, conversions to open surgery, and other complications have been widely discussed and published. A number of strategies have been recommended to minimize or prevent the occurrence of these problems, and also to prevent other adverse sequelae such as persistently troublesome postoperative dysphagia or gas bloat syndrome [19]. During a 10-year period in Finland, laparoscopic fundoplication had a prevalence rate of 1.3% for life-threatening complications, and a prevalence rate of 1.2% for non-life-threatening complications [17].

The goal of this study was to identify risk factors that would be helpful in preoperatively identifying patients with possible complications from laparoscopic Nissen fundoplication. This information would be of use in the preoperative counseling of reflux patients, and it could be used potentially to identify patients who would benefit from continued medical therapy.

Materials and methods

Between March 1993 and April 1999, 132 patients underwent laparoscopic Nissen fundoplication. Two patients died in the meantime (deaths not related to disease), and four patients could not be reached. Consequently, 126 patients (95%) were included in this study. The minimal follow-up period after the operation was 6 months. The patients had severe or resistant GERD requiring continuous or increasing medical treatment. Some of the patients were refractory to medical treatment or experienced side effects from medical therapy. Another indication for surgery was the existence of a hiatal hernia with GERD. Previous abdominal surgery was not an absolute exclusion criterion.

Preoperative assessment included upper gastrointestinal endoscopy in all the patients as well as barium esophagogastric study, esophageal manometry, and 24-h pH monitoring in selected patients with suggested motility disorders or reflux without esophagitis. All the operations were performed by the same three surgeons at two different hospitals. The operation technique and follow-up assessment were standardized. After the introduction of five trocars in the upper abdomen, the hiatus and distal esophagus were dissected free. Ligation of the short gastric vessels, which enables mobilization of the fundus, was not systematically performed. A 3- to

Table 1. Intraoperative complications and conversions

Complication	Intraoperative complication (<i>n</i> = 9; 6.9%) <i>n</i> (%)	Conversion (<i>n</i> = 6; 4.8%) <i>n</i> (%)
Hemorrhage	3 (2.3)	2 (1.5)
Gastric perforation	3 (2.3)	2 (1.5)
Esophageal perforation	2 (1.5)	2 (1.5)
Pneumothorax	1 (0.8)	—

4-cm-long fundoplication of 360°, calibrated after insertion of a 12- to 14-mm gastric tube, was performed and, if judged necessary, fixed to the right crus with one additional suture. The crura were not closed routinely. A clear liquid diet was begun 6 h after the procedure and advanced as tolerated.

All the patients were reviewed retrospectively with the help of the charts, and all answered a standardized questionnaire or were contacted by phone calls. The review sought to establish the presence or absence before and after the operation of the following symptoms: epigastric pain, nausea, vomiting, bloating, diarrhea, constipation, dysphagia for solid and liquid, nocturnal coughing, and regurgitation. The ability to relieve bloating and to vomit also were determined as well as whether a normal diet was being consumed. Patients reporting symptoms lasting longer than 6 months after the operation were considered to have persistent symptoms. The outcome of surgery was determined using modified Visick grading with scores of I to IV. Patients also were asked to score an overall assessment of satisfaction with the operative outcome using the following choice options: satisfied, moderately satisfied, dissatisfied).

Three groups of patients were distinguished:

1. Patients without complications
2. Patients with intraoperative complications
3. Patients with postoperative complications (including long-term complications and severe, persistent symptoms).

The patient demographics, the results of preoperative investigations, the pre- and postoperative symptoms, and the outcomes were analyzed and compared among these three groups. Statistical analyses were carried out using the *t*-test for matched studies, the nonparametric Wilcoxon rank test for quantitative variables, and the chi-square test and Fisher's exact test for qualitative variables. Statistical significance was accepted at a *p* value less than 0.05.

Results

The study included 70 men and 56 women with a mean age of 47.9 years (range, 19.7–83.7 years). Patients responded to the questionnaire or phone calls an average of 3.5 years (range, 0.5–6.8 years) after the operation. All the patients had been admitted to the hospital 1 day before surgery. The period of hospitalization had varied from 3 to 29 days (average, 4.9 days). The overall operative time had varied from 65 to 240 min (average, 122 ± 33 min). In all, 8 patients had undergone a previous upper abdominal operation (5 patients for gallstones and 3 patients for gastroduodenal ulcer) and 25 patients had undergone a previous lower abdominal operation (22 appendectomies, 4 hysterectomies, 3 colectomies). Nine intraoperative complications in 9 patients (Table 1) and 17 postoperative complications in 16 patients had occurred (Table 2).

Intraoperative complications and conversions (Table 1)

Of the three hemorrhages, two were from sectioning of an anomalous left gastric artery, and one involved persistent

Table 2. Postoperative complications in 16 patients (*n* = 17)

Complication	<i>n</i> (%)
Severe persistent dysphagia	5 (3.8)
Failure	4 (3.1)
Pneumonia	2 (1.5)
Incisional hernia	2 (1.5)
Small intestine perforation	1 (0.8)
Fundoplication herniation	1 (0.8)
Intraabdominal abscess	1 (0.8)
Gastric ulcer	1 (0.8)

blood oozing from division of adhesions. Conversion to laparotomy was needed in two patients to control the bleeding. None of the patients required blood transfusion during the follow-up period. Three gastric and two esophageal perforations occurred, requiring conversion to open surgery in two cases each. One gastric perforation was sutured laparoscopically. The patient had good recovery, with no further complication. One left pneumothorax was identified and drained. There were five conversions in the first 50 patients and one conversion in patients 51 to 100.

Postoperative complications (Table 2)

A total of 33 patients (26.2%) reported dysphagia 3 months after the operation, but these symptoms had persisted in only 9 patients (7.1%) at 6 months. Of these 9 patients, 5 presented with severe dysphagia. One inflammatory stenosis occurred during the hospitalization, which was treated successfully with steroids. Two stenosis needed esophageal dilation, and one required reoperation by laparoscopy. The crura were fibrotic and narrowed the gastroesophageal junction. Finally, one patient required continuous medication and a special diet. At this writing, he has refused a reoperation. Failure of the operation, with reappearance of the same symptoms, was seen in another four patients. Insufficiency of the fundoplication was diagnosed in two patients, who underwent reoperation, one by laparoscopy after 6 years and one by laparotomy after 4 months. Once, a patient's symptoms were treated only with medication, and one psychotic patient did not undergo surgery again. Postoperative pneumonia occurred in two cases and was treated successfully with antibiotics. One patient presented with peritonitis 36 h after an uneventful Nissen procedure. At laparotomy, a small intestine perforation was identified and sutured. The patient had an uneventful recovery. One intra-abdominal abscess was diagnosed 7 days after the operation and treated conservatively without drainage. The patient recovered well. However, 8 weeks later, he presented with a gastric ulcer, which was treated conservatively. One patient with a huge hiatal hernia presented with severe regurgitation 28 weeks after the initial operation. A barium contrast study showed an intrathoracic herniation of the fundoplication, and the patient underwent reoperation by laparoscopy. At this writing, she is free of symptoms. Two incisional hernias were corrected. No operation-related death occurred during the follow-up period.

The three groups were similar in age, gender anesthetic American Society of Anesthesiology (ASA) score, incidence of previous abdominal surgery, duration of symp-

Table 3. Patient demographics

	No complication	Intraoperative complication	Postoperative complication
No. of patients	101	9	16
Male : female	57:44	7:2	6:10
Age (mean years)	48.3	41.5	48.6
BMI (mean kg/m ²)	28.7 ± 6.1	32.4 ± 4.9 ^a	33.6 ± 7.5 ^a
ASA n (%)			
Grade I	43 (42.5)	4 (44.4)	7 (43.8)
Grade II	48 (47.5)	5 (55.6)	7 (43.8)
Grade III	10 (10)	—	2 (12–4)
Operative time (mean min)	118 ± 30	123 ± 21	142 ± 51 ^a
Hospital stay (mean days)	4.2	4.9	5.6
Esophagitis n (%)			
None	11 (10.9)	1 (11.1)	4 (25)
Grade I	16 (15.8)	1 (11.1)	1 (6.3)
Grade II	61 (60.5)	5 (55.6)	8 (50)
Grade III	6 (5.9)	—	3 (18.7)
Grade IV	7 (6.9)	2 (22.2)	—
Hiatal hernia (%)			
None	19 (18.8)	2 (22.2)	6 (37.5)
Yes	82 (81.2)	7 (77.8)	10 (62.5)

^a $p < 0.05$

BMI, body mass index; ASA, American Society of Anesthesiology

toms, and medications consumed before surgery. Also no difference was seen in the preoperative severity of esophagitis or in the presence or absence of a hiatal hernia (Table 3). As compared with the group that had no complications, operation time was slightly higher in the group with intraoperative complication and significantly higher ($p = 0.0088$) in the group with postoperative complication. No more technical problems during the operation were seen in the latter group. Previous abdominal surgery and concurrent operation, such as cholecystectomy and others, were similar in all three groups. Patients in the groups with intraoperative and postoperative complications presented a significantly, increased body mass index (BMI) ($p = 0.0051$ and $p = 0.0018$, respectively) compared with the patients who had no complications.

Analysis of the presence or absence of preoperative symptoms (Table 4) showed no significant difference among the three groups. Nearly all the patients presented with epigastric pain and dysphagia. Specific fundoplication symptoms such as inability to vomit or belch were reported with a similar frequency in all three groups. However, only one-fifth of these patients stated that inability to vomit had a detrimental effect on their quality of life and alimentary habit.

Other symptoms after fundoplication such as dysphagia, postprandial fullness, bloating, and flatulence are listed and compared in Table 4. The Visick grade and subjective outcome were similarly good in all three groups (Table 5). There also was no significant difference in the willingness to undergo the procedure again (89% versus 90% versus 84%) should similar preoperative circumstances arise. Most patients said they would recommend the operation to others.

Discussion

Three factors determine the successful outcome after an antireflux operation for GERD : indication for surgery,

choice of operative procedure, and quality of the operation [5]. Wetscher et al. [20] believed that Nissen fundoplication is not the proper antireflux procedure for patients with poor esophageal peristalsis and preferred a tailored approach. Another study demonstrated that esophageal dysmotility is no contraindication for laparoscopic Nissen fundoplication [2]. All the patients in this review had undergone surgery by the same, standardized technique well known by all three surgeons from the open Nissen fundoplication procedure. During at least the first 30 procedures, each surgeon was assisted by one of his or her colleagues.

The conversion rate in the literature varies from 1.8% to 9.8% [3, 4, 19, 21]. The principal causes for conversion are difficulties with exposure and bleeding [3]. Some have described adhesions and inability to reduce the hiatal hernia as the main cause of conversion [4, 21]. The most frequent intraoperative complication is pneumothorax [4]. Perforation of the stomach or esophagus occurs in less than 1% of patients [21].

We experienced only one pneumothorax, and our total conversion rate was 4.8%, which resulted from bleeding or perforation of the stomach or the esophagus at an early stage in our experience. The effect of the learning curve on the outcome has been demonstrated clearly in several studies [3, 16]. The duration of surgery, the rate of conversion, the duration of hospitalization, and the morbidity decreases with greater experience of the surgeon. In this study intraoperative and postoperative complications occurred mainly in patients who underwent surgery at the beginning of our experience. The overall morbidity of 20% (including all intra- and postoperative complications) seems high, but the learning curve of all three surgeons clearly demonstrates a decrease of complications with greater experience. After experience with at least 30 operations on the part of each surgeon, the cumulative morbidity decreased to 2.9%. The surgeon himself was no risk factor for complication.

In the literature the interval between the initial laparoscopic fundoplication and the reoperation is quite short (<2

Table 4. Preoperative (preop) and postoperative (postop) symptoms

Complication	No complication (n = 101)		Intraoperative complication (n = 9)		Postoperative complication (n = 16)	
	Preop n (%)	Postop n (%)	Preop n (%)	Postop n (%)	Preop n (%)	Postop n (%)
Epigastric pain	93 (92.1)	4 (3.9)	9 (100)	—	15 (93.4)	5 (31.3)
Nausea	12 (11.9)	1 (0.9)	2 (22.2)	—	4 (25)	1 (6.3)
Vomiting	30 (29.7)	0	2 (22.2)	—	8 (50)	1 (6.3)
Bloating	77 (76.2)	25 (24.8)	7 (77.8)	1 (11.1)	15 (93.8)	7 (43.7)
Diarrhea	14 (13.8)	9 (8.9)	1 (11.1)	1 (11.1)	2 (12.5)	2 (12.5)
Constipation	9 (8.9)	4 (3.9)	3 (33.3)	1 (11.1)	2 (12.5)	2 (12.5)
Dysphagia total	93 (92.1)	—	9 (100)	—	15 (93.8)	—
For solids	47 (46.5)	4 (3.9)	—	—	11 (68.8)	5 (31.3)
For liquids	46 (45.5)	—	9 (100)	—	4 (25)	—
Nocturnal cough	9 (8.9)	—	—	—	—	—
Regurgitation	24 (23.8)	1 (0.9)	2 (22.2)	1 (11.1)	3 (18.8)	2 (12.5)
Can relieve bloat	—	90 (89)	—	7 (77.8)	—	14 (87.5)
Can vomit	—	86 (85.1)	—	7 (77.8)	—	14 (87.5)
Eats normal diet	—	96 (95)	—	8 (88.9)	—	11 (68.8)

Table 5. Subjective outcome and Visick grading

	No complication (n = 101)	Intraoperative complication (n = 9)	Postoperative complication (n = 16)
<i>Visick grade</i>			
I	82 (81.2)	8 (88.9)	11 (68.8)
II	17 (16.8)	1 (11.1)	1 (6.2)
III	2 (2)	—	4 (25)
IV	—	—	—
<i>Subjective outcome</i>			
Satisfied	80 (79.2)	8 (88.9)	3 (18.8)
Moderately satisfied	17 (16.8)	1 (11.1)	6 (37.5)
Dissatisfied	4 (4)	—	7 (43.7)

years in 90% of patients). Similar to open fundoplication, most laparoscopic fundoplications fail early. Published failure rates for laparoscopic Nissen fundoplication are 2% to 17% [3], depending on the definition of failure and the experience of the surgeons. The total failure rate in this study was 7.9% with a mean follow-up period of 3.5 years. This relative long follow-up period does not guarantee that all failures have been included. Only long-term results over 10 years or more will prove the value of the laparoscopic Nissen technique.

Fundoplication herniation seems to be the Achilles' heel of laparoscopic fundoplication [11]. It was found only once in this study. Fixation of the fundoplication to the under-surface of the diaphragm seems less effective in preventing this complication than thorough esophageal mobilization and crural closure [11]. The crura were not routinely closed in this study, but the fundoplication was attached to the right crus in 74% of the cases. Also, the fundoplication was attached by the last inferior point to the anterior wall of the stomach to prevent any rotation or slippage.

Altogether, four patients underwent reoperation (1 with fundoplication herniation, 2 with insufficiency of the fundoplication, 1 with severe dysphagia), three of the four laparoscopically. Hunter et al. [11] demonstrated that laparoscopic revision is as successful as open fundoplication revision and can be accomplished with fewer complications.

The predisposing factors for recurrence are nonclosure of the crura, nonfixation of the valve, a valve under tension, endobranchyoesophagus, and obesity [3, 10]. The first three causes can be influenced by the surgeon, but the latter two are independent of the surgeon. Obese patients were significantly more frequent statistically in the groups with intraoperative and postoperative complications than in the group without complications. Table 6 compares all the patients who had BMI less than 30 kg/m² with the patients who had a BMI greater than 30 kg/m². Clearly, more intraoperative and postoperative complications occurred in patients with a BMI greater than 30 kg/m², although the final outcome (Visick score and subjective result) was not influenced. This probably can be explained by the fact that most of the patients were not aware of the intraoperative complication because it had no personal consequence, and all of the patients had been clearly informed preoperatively about the possibility of conversion to open surgery.

Only 10 of the 16 postoperative complications in this study influenced the final outcome and needed reoperation or medical treatment. These complications therefore were significant to the patient. The most important factor in patient satisfaction after antireflux surgery remains the abolition of preoperative symptoms [18]. Obesity is associated with many comorbidities that contribute to multiple organ dysfunction, illness, and shortened life span. It generally is accepted that obesity is a strong risk factor for GERD [6, 15], although a recent population-based study reported no relation between BMI and GERD [14]. Weight reduction alone may not be justifiable as an antireflux therapy, but it can improve symptoms of GERD [7] and certainly reduces comorbidity. Further studies will prove the encouraging reports of a single operation for morbid obesity and GERD with hiatal hernia by a Lap-Band® (Bio Enterics Corporation, Carpinteria, CA) placement [1].

Laparoscopic Nissen fundoplication is associated with a small but significant incidence of persistent and troublesome postoperative dysphagia. Temporary postoperative dysphagia is found in approximately 50% of patients 1 week after surgery and persists for 3 months in 2% to 26% [2, 8,

Table 6. Results regarding BMI less than 30 kg/m² and BMI greater than 30 kg/m²

	BMI <30 (n = 75) n (%)	BMI >30 (n = 51) n (%)
No complication	66 (88)	35 (68)
Intraoperative complication	3 (4)	6 (12)
Postoperative complication	6 (8)	10 (20)
<i>Visick grade</i>		
I	59 (78)	42 (82)
II	12 (16)	7 (14)
III	4 (5)	2 (4)
IV	—	—
<i>Subjective outcome</i>		
Satisfied	57 (76)	38 (74)
Moderately satisfied	14 (19)	10 (20)
Dissatisfied	4 (5)	3 (6)

BMI, body mass index

12, 13]. Postoperative dysphagia is difficult to predict and does not depend on surgical technique [21]. An older study, however, demonstrated a correlation between surgical technique and a higher rate of early and persistent postoperative dysphagia, [12]. Patients with division of short gastric vessels had a reduced risk of postoperative dysphagia, whereas gender, preoperative report of dysphagia, endoscopic grade of esophagitis, esophageal motility, and lower esophageal sphincter pressure seemed not to have an influence in one study [8].

Recently, Kamolz et al. [13] reported that the subjective degree of dysphagia and the perceived impairment as a result of laparoscopic antireflux surgery can be predicted according to the personality of the patient. In a study by Heron et al. [9], the sole risk factor for postoperative dysphagia was a report of difficulty swallowing preoperatively ($p = 0.029$). In the current study, preoperative dysphagia for solid food also was more frequent in the group that had postoperative complications, as compared with the group that had no complications, but no significant difference was noted ($p = 0.09$). Generally, all preoperative symptoms decreased less in the two groups with complications (Table 4), but no preoperative symptom could be detected as a significant risk factor for complications.

In summary, the rate of complications of laparoscopic Nissen fundoplication for GERD is low, decreases with the surgeon's experience, but remains difficult to predict. Neither preoperative studies nor preoperative symptoms seem to predict complications. In this study, an increased BMI was a risk factor for complications of laparoscopic Nissen fundoplication. The patient with increased BMI therefore should be appropriately counseled regarding the greater likelihood of intraoperative or postoperative complications.

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